

REMARKS

Status of the Claims

After appealing the Examiner's rejection of claims 1, 3, 5, 6, and 10-31, the Decision on Appeal found:

The decision of the Examiner to reject claims 1, 3, 5, 6, and 10-31 is reversed.

We enter new grounds of rejection of claims 1, 3, 5, 6, and 10-31 under 35 U.S.C. § 112, second paragraph.

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (2007). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner... .

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record... .

Applicant hereby requests that prosecution be reopened and that the pending claims be reconsidered in light of the comments and evidence provided herein. In addition, Applicant has added new claims 32 to 44.

New Grounds of Rejection

In the Decision on Appeal, the Board found the new ground of rejection that claims 1, 3, 5, 6, and 10-31 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Decision specifically states:

Independent claim 1 requires a *banana-shaped* unitary body as depicted in Figure 4 of Appellant's Drawings. See also Spec. 4, I. 3.

Figure 4 of Appellant's Drawings is reproduced below:

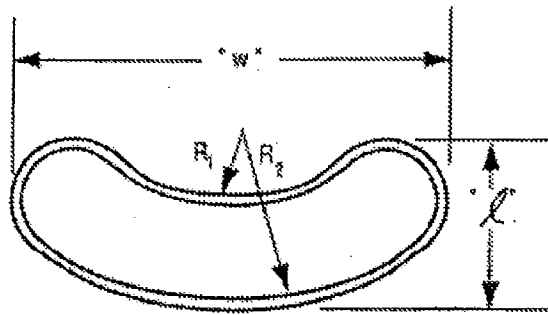


Figure 4 of Appellant's Drawings depicts the length "l", the width "w", the front arc radius of curvature "R₁", and the back arc radius of curvature "R₂" of a spinal implant.

Appellant "defines 'banana' as follows: 'the elongated often curved and usu. tapering fruit of the banana plant.'" App. Br. 8. ¹As an example, of a banana shape, we provide the following Figure:²



The Figure depicts a banana.

After comparing the shape of Appellant's claimed "banana-shaped" unitary body (as per Figure 4 of Appellant's Drawings) with the definition provided by Appellant for a banana shape and the Figure, we do not find that Appellant's illustrated spinal implant is *banana-shaped*, as required by independent claim 1. Although the shape shown in Figure 4 of Appellant's Drawings is elongated and curved, it is not tapering.

Hence, claim 1 "do[es] not define the invention (i.e., the subject matter which the applicant regards as his invention) with a reasonable degree of particularity." *In re Hammack*, 427 F.2d 1378, 1382 (CCPA 1970). In other words, we conclude that *banana-shaped* as used in the claims, when construed in view of Appellant's Figure 4, lacks sufficient precision so that one endeavoring to practice the invention could not determine the metes and bounds thereof.

¹Like Appellant, we find that an ordinary and customary meaning of the term "banana" is "an elongated usu. tapering tropical fruit." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th Ed. 1997).

² THE MACMILLAN VISUAL DESK REFERENCE, Tropical fruits 1547 (1993).

In light of the above, we conclude that claim 1, which includes the *banana-shaped* limitation, and claims 3, 5, 6, and 10-31 which depend from claim 1, are inherently inconsistent with the description that appears in Appellant's Specification and Drawings.

Applicant traverses:

- First, the Board contradicts itself and the facts and gets the result wrong;
- Second, given the rejection, Applicant submits evidence showing that persons of ordinary skill in the art refer to prostheses of this very shape as “banana-shaped;”
- Third, given that the Applicant is allowed to be its own lexicographer, to the extent that “banana-shaped” unclear (and Applicant believes it is not), Applicant makes it clear by reference to the banana shapes of the Figures; and
- Fourth, the claims sufficiently define the banana shape even apart from the term “banana-shaped.”

Finally, Applicants add new claims that leave out the term “banana-shaped.”

A. The Board Was Wrong

The Board concluded that the claims that included the term “banana-shaped” were indefinite because the implant of Figure 4 of the application, according to the Board, is not banana-shaped. This result is contrary to the law, contrary to the facts, and contrary to the definition of “banana” adopted by the Board and by the Applicant.

The Board relied on the dictionary definition of “banana” and expressly adopted it. That definition is: “the elongated often curved and usu. tapering fruit of the banana plant.” To be clear, the definition of “banana” says that bananas are usually tapering. The Board then concluded that calling the device of figure 4 “banana-shaped” is a misnomer because the device of figure 4 does not taper. This logic necessarily fails because *the definition of banana does not require it to taper*.

The Board is wrong and the term “banana-shaped” is not misapplied by the Applicant.

B. Evidence Shows that People of Ordinary Skill in the Art Routinely Refer to Prostheses having the Shape Shown in Figure 4 as “Banana-Shaped”

People of ordinary skill in the art routinely refer to prostheses of the shape shown in Figure 4 as “banana-shaped.” Applicant attaches here to (as Exhibit A), for example, a paper entitled “Comparison of cage designs for transforaminal lumbar interbody fusion: A biomechanical study,” W. Cho et al., 23 Clinical Biomechanics 979 (2008). The cage designs that are compared include “banana shape” cages:

- The purpose of this study is to compare three popular TLIF implant designs (Stryker AVS PL, AVS TL and the Medtronic Capstone) with different lengths and shapes (flat or biconvex, straight or banana shape) in terms of biomechanical stability on human cadaveric models. p. 980
- The AVS TL has a banana shape where as the AVS PL has a shape with flat superior and inferior surfaces. p. 980.

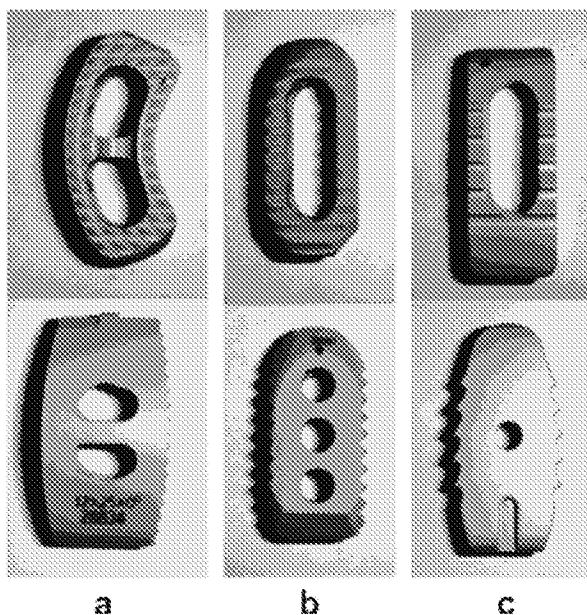


Fig. 1. Three types of TLIF cages were evaluated for their biomechanics including (a) banana shape (b) flat and straight shape (c) biconvex and straight shape.

The Discussion portion of the paper specifically compares the banana shaped cages to other shapes:

- In addition to the variety in material choices, a number of structural designs of lumbar fusion cages have been developed. In general, these designs include

threaded cylindrical cages, titanium mesh cages, wedged structural allograft, banana shaped cages and bullet shaped cages. p. 982.

- Recently, the majority of commercially available TLIF cages, such as AVS (Stryker Spine), Verte-stack Capstone and Crescent (Medtronic), Lumbar I/F and Leopard (Depuy Acromed), and TraXis (Spinal Concepts), have either banana shape or straight shape. These cages are often made from PEEK. The banana shaped cages are preferably placed in the anterior side of disc space. p. 982.

There can be no doubt that persons of ordinary skill in this art know what a banana shaped cage is. As can be seen in the top half of Figure (a) from the article, it is exactly the same shape as illustrated in Figure 4 of the application (and it has no taper).

Searching the literature further shows that persons of ordinary skill in the art refer to banana-shaped prostheses, especially for insertion using a TLIF procedure. A literature search reveals at least the following hits:

CAUTION: Federal (USA) Law restricts this device to sale by or on

File Format: Microsoft Word - View as HTML

Petra TLIF **Cage** is a **banana** shaped **cage** with pyramidal teeth to resist implant ... When more than two involved **spinal** levels are treated, longer operative ...
calvaryspine.com/docs/Petra_TLIF_Package_Insert_3-10.docx

Spine Surgery: Tricks of the Trade - Google Books Result

Alexander R. Vaccaro, Todd J. Albert - 2008 - Medical - 321 pages

... and flexion/extension lumbosacral **spine** radiographs are necessary. ... when placing a **banana**-shaped **cage** through a unilateral TLIF approach and is often
books.google.com/books?isbn=1588905195...

Comparison of low back fusion techniques: transforaminal lumbar ...

by CD Cole - 2009 - Cited by 2 - Related articles

However, single "**banana**"-shaped or rectangular devices have been designed to cover A biomechanical comparison, including a new threaded **cage**. **Spine**.

www.ncbi.nlm.nih.gov › ... › v.2(2); Jun 2009 - Similar

Radiographic and Clinical Outcomes After Instrumented Reduct ...

by N Goyal - 2009 - Cited by 1 - Related articles

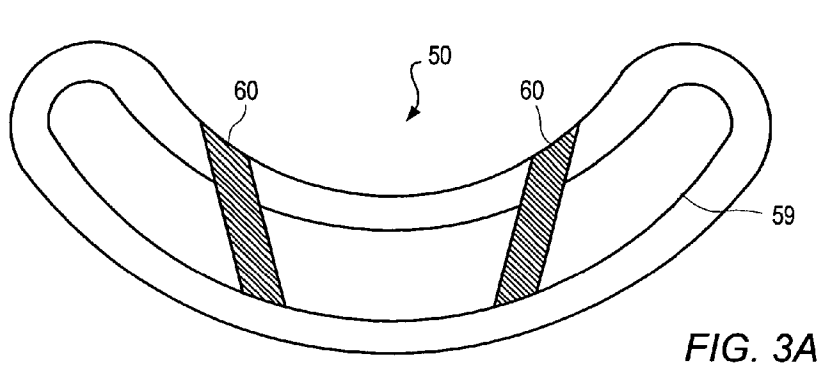
As with many other conditions of the **spine**, radiographic findings such as ... carbon fiber reinforced peek **banana**-shaped **cage**) was used in all patients. ...

journals.lww.com › Home › July 2009 - Volume 22 - Issue 5

Published US patent application 2007/0073406 also discusses banana-shaped prostheses. In fact, this application states:

The expandable implants may have various shapes, such as round, square, rectangular, banana-shaped, kidney-shaped, or other similar shapes. [Abstract]

Thus, this application expressly recognizes the banana-shape, and further understands that it is distinct from the kidney-shaped prior art cited by the Examiner. The application goes on to expressly show a banana-shaped prosthesis as “FIG. 3 a is a top view of a banana-shaped, expandable intervertebral implant of the present invention”:



This figure is clearly banana-shaped in the same manner as Figure 4 of the present application (and it has no taper).

Again, there can be no legitimate doubt, persons skilled in this art use the term “banana-shaped” in exactly the same way as the application. A person of ordinary skill in the art would find no ambiguity in the term banana-shaped as applied, and so that term cannot be indefinite.

C. Applicant is Entitled to be Its Own Lexicographer and May Define Banana-Shaped as the Shape of Figure 4

Even if the Board were right (and it is not right), it is hornbook law that the Applicant is entitled to be its own lexicographer. If Applicant states clearly in the specification (as it does) that Figure 4 is banana-shaped, then Figure 4 is banana-shaped and the Board’s conclusion is wrong. (See, e.g., MPEP 2111.01 relating to the “plain meaning” of claim terms and the relationship between plain meaning and lexicography.) In this case, Applicant believes that lexicography is not required because the ordinary English meaning is consistent with the understanding of persons of ordinary skill in the art, and is further consistent with the use of the

term in the specification. Even if this were not the case, the claim term would not be indefinite because the Applicant has defined it with respect to Figure 4.

D. The Claims Sufficiently Define the Shape of the Banana-Shape

“Banana-shaped” is not the only limitation on the shape of the prosthesis in the claims. Claim 1 recites front and back arcs. Claims 3, 5, and 6 relate the radii of the front and back arcs. Claims 24 to 27 recite specific dimensions for the banana shape that further distinguish the prior art. Claims 30 and 31 specifically recite the thinness of the banana shape which also distinguishes over prior art.

New claim 32 leaves out the term “banana-shaped,” but instead refers to the shape as a curved ring (see, application at page 6, lines 13-14 and page 7, lines 5-8). The claim also recites that the front and back arcs are curved in the same direction (see, application at Figure 4 and the discussion of R1 and R2 at pages 6-7). The claim also includes the ration of width to length that defines the thinness of the shape.

These shapes are sufficiently defined, regardless of the term banana-shape, to render the boundaries of the claims clear and definite.

E. The Board Failed to Address the Prior Art Arguments

Despite the fact that the MPEP prohibits examiners from doing this, the Board made its incorrect indefiniteness rejection – and used that rejection as an excuse not to expressly address the prior art. (See, MPEP 2173.06, preferring that claims rejected as indefinite also be rejected over prior art if appropriate in order to avoid the kind of piecemeal examination that the Board seems to have ordered here).

Accordingly, Applicant relies on the arguments provided in its Appeal Brief and Reply to address the prior art rejections to the extent that those rejections are still outstanding.

CONCLUSION

In view of the remarks above, Applicant submits that claims 1, 3, 5, 6 and 10-44 are in condition for allowance, and allowance thereof is respectfully requested. Patentee encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-706.

Respectfully submitted,

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